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(*pro hac vice* applications to be filed)

*Attorneys for Par Sterile Products, LLC;
Par Pharmaceutical, Inc.; and Par
Pharmaceutical Companies, Inc.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

FRESENIUS KABI USA, LLC,

Plaintiff,

v.

PAR STERILE PRODUCTS, LLC, PAR
PHARMACEUTICAL, INC., and PAR
PHARMACEUTICAL COMPANIES, INC.,

Defendants.

Civil Action No.: Case 2:15-cv-03852-CCC-MF

**DEFENDANTS' ANSWER AND
COUNTERCLAIMS**

Defendants Par Sterile Products, LLC ("Par Sterile"), Par Pharmaceutical, Inc. ("Par Pharmaceutical, Inc.") and Par Pharmaceutical Companies, Inc. ("Par Pharmaceutical, Co.") (collectively, "Par"), by and through their undersigned counsel, hereby respond to plaintiff Fresenius Kabi USA, LLC's ("Fresenius") complaint and states as follows:

NATURE OF THE ACTION

1. The complaint purports to allege an action under the patent laws of the United States, Title 35, United States Code, in response to the filing of an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration (“FDA”). Otherwise denied.

THE PARTIES

2. Par lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies the allegations on that basis.

3. Par Sterile Products, LLC admits it is organized under the laws of the state of Delaware with a place of business in Parsippany, New Jersey. Par denies the remaining allegations contained in paragraph 3.

4. Par Pharmaceutical, Inc. admits that it is a corporation organized under the laws of the state of Delaware with a place of business in Woodcliff Lake, New Jersey. Par denies the remaining allegations in paragraph 4.

5. Par Pharmaceutical Companies, Inc. admits it is a corporation organized under the laws of the state of Delaware with a place of business in Woodcliff Lake, New Jersey. Par denies the remaining allegations in paragraph 5.

6. Admitted.

JURISDICTION AND VENUE

7. The allegations in paragraph 7 state legal conclusions to which no answer is required. Otherwise denied.

8. The allegations in paragraph 8 state legal conclusions to which no answer is required. To the extent an answer is required, Par Sterile does not dispute subject matter

jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). Par does not respond to the legal conclusions and Par denies the remaining allegations.

9. The allegations in paragraph 9 state legal conclusions to which no answer is required. To the extent an answer is required, Par Sterile does not contest personal jurisdiction of this Court for the purpose of this action only. Otherwise denied.

10. The allegations in paragraph 10 state legal conclusions to which no answer is required. To the extent an answer is required, Par Sterile does not contest venue in this District for the purposes of this action only.

THE PATENT-IN-SUIT

11. Par Sterile admits that Exhibit A of the Complaint purports to be a version of U.S. Patent No. 9,006,289 (the '289 patent), titled "Levothyroxine Formulations," and apparently issued on April 14, 2015. Par denies that the '289 patent was duly and legally issued. Par lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations and therefore denies the allegations on that basis.

12. Par lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies the allegations on that basis.

13. Admitted.

14. Fresenius holds New Drug Application ("NDA") No. 202231 for levothyroxine sodium, and the Orange Book lists the '289 patent for this NDA. The remaining allegations in paragraph 14 state legal conclusions to which no answer is required.

15. The Orange Book lists the '289 patent as expiring on October 3, 2032. Par lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations and therefore denies the allegations on that basis.

PAR'S ANDA NO. 205366

16. Par Sterile admits that JHP Pharmaceuticals, LLC submitted ANDA No. 205366 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetics Act (21 U.S.C. § 355(j)), seeking FDA approval to engage in commercial manufacture, use, or sale of generic 100 mcg/vial, 200 mcg/vial, and 500 mcg/vial levothyroxine sodium powder for injection (“ANDA products”). Par denies the remaining allegations in paragraph 16.

17. Par Sterile admits that ANDA No 205366 contains a Paragraph IV certification that the '289 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by ANDA No. 205366. Par denies the remaining allegations in paragraph 17.

18. Par Sterile admits that Par Sterile owns ANDA No. 205366, and Par denies the remaining allegations contained in paragraph 18.

19. Par lacks knowledge or information sufficient to form a belief about the truth of the allegations and therefore denies the allegations on that basis.

20. Par Sterile admits it will comply with the applicable laws and regulations to engage in the commercial manufacture, use, and sale of its ANDA products. Par lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations and therefore denies the allegations on that basis.

21. Par Sterile admits it will comply with the applicable laws and regulations to engage in the commercial manufacture, use, and sale of its ANDA products. The remaining allegations in paragraph 21 state legal conclusions to which no answer is required.

22. Par Sterile admits that its Paragraph IV certification states that the claims of the '289 patent are invalid, unenforceable, and/or will not be infringed by the commercial

manufacture, use, or sale of products described by ANDA No. 205366. Par denies the remaining allegations in paragraph 22.

23. The allegations in paragraph 23 state legal conclusions to which no answer is required. To the extent an answer is required, Par Sterile admits that it seeks approval of its ANDA products, however, Par lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations and therefore denies the allegations on that basis.

24. Par denies that it was aware of the '289 patent when JHP Pharmaceuticals, LLC submitted ANDA No. 205366 to the FDA. Par Sterile admits that it was aware of the '289 patent when it submitted its Paragraph IV certification directed to the '289 patent. Par denies the remaining allegations in paragraph 24.

25. Par Sterile admits JHP Pharmaceuticals, LLC submitted ANDA No. 205366 to the FDA. Otherwise denied.

26. Denied.

COUNT I: INFRINGEMENT OF THE '289 PATENT – ANDA SUBMISSION

27. Par repeats and incorporates its answers to paragraphs 1–26 as if fully set forth herein.

28. This paragraph state a legal conclusion for which no response is required. To the extent a response is required, denied.

29. Denied.

30. Denied.

31. Denied.

32. Denied.

33. Denied.

34. Denied.

35. Denied.

36. Denied.

37. Denied.

38. This paragraph states a legal conclusion for which no response is required. To the extent a response is required, denied.

39. Denied.

40. Par admits it will comply with the applicable laws and regulations to engage in the commercial manufacture, use, and sale of its ANDA products. The remaining allegations in paragraph 40 state legal conclusions to which no answer is required.

41. Denied.

42. Denied.

COUNT II: INFRINGEMENT OF THE '289 PATENT – DECLARATORY JUDGMENT

43. Par repeats and incorporates its answers to paragraphs 1–42 as if fully set forth herein.

44. The allegations in paragraph 44 state legal conclusions to which no answer is required. To the extent an answer is required, denied.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

49. Denied.

50. Denied.

RELIEF SOUGHT

Par denies that Fresenius is entitled to any of the relief requested in paragraphs A–I of the complaint.

DEFENSES TO PLAINTIFF’S COMPLAINT

Without any admission as to the burdens of proof, or as to any of the allegations in plaintiff’s complaint, Par states the following:

FIRST DEFENSE (Noninfringement)

1. Par will not directly, indirectly, contributorily, and/or by inducement infringe either literally or under the doctrine of equivalents any valid claim of the ’289 patent under any section of 35 U.S.C. § 271.

SECOND DEFENSE (Invalidity)

2. The claims of the ’289 patents are invalid for failure to comply with 35 U.S.C. §§ 101, 102, 103, and/or 112.

THIRD DEFENSE (Lack of Subject Matter Jurisdiction)

3. The Court lacks subject matter jurisdiction over claims asserted against Par Pharmaceutical Companies, Inc.

FOURTH DEFENSE (Lack of Subject Matter Jurisdiction)

4. The Court lacks subject matter jurisdiction over claims asserted against Par Pharmaceutical, Inc.

FIFTH DEFENSE
(Failure to State a Claim)

5. Fresenius's allegations of indirect infringement fail to state a claim for which relief may be granted.

COUNTERCLAIMS

Par Sterile, for its Counterclaims against Fresenius Kabi USA, LLC ("Fresenius" or "counterclaim defendant"), alleges as follows:

1. Par Sterile is a Delaware limited liability company with a place of business in Parsippany, New Jersey.

2. Upon information and belief, and on Fresenius's complaint, Fresenius is a corporation organized under Delaware law having its corporate headquarters at Three Corporate Drive, Lake Zurich, Illinois 60047. Fresenius alleges it owns the '289 patent.

3. This is a declaratory judgment action under the patent laws of the United States, 35 U.S.C. § 1, *et seq.* Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

4. An actual and justiciable controversy therefore exists between the parties.

5. The Court has personal jurisdiction over counterclaim defendant based on its contacts with the District of New Jersey relating to the subject matter of this action, including having filed this suit.

6. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1400(b).

COUNT I
(Declaratory Judgment of Noninfringement of the '289 Patent)

7. Par Sterile incorporates by reference, as if fully set forth herein, the preceding paragraphs of its Answer and Counterclaims.

8. Par Sterile has not infringed and is not infringing any valid claim of the '289 patent, literally or under the doctrine of equivalents either directly or indirectly, and has not induced infringement or contributed to infringement by others.

9. A definite and concrete, real and substantial, justiciable controversy exists between Par Sterile and Fresenius, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of noninfringement of the '289 patent.

10. Par Sterile is entitled to a declaratory judgment that the '289 patent is not infringed.

COUNT II
(Declaratory Judgment of Invalidity of the '289 Patent)

11. Par Sterile incorporates by reference, as if fully set forth herein, the preceding paragraphs of its Answer and Counterclaims.

12. Each and every claim of the '289 patent is invalid for failure to comply with the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.

13. A definite and concrete, real and substantial, justiciable controversy exists between Par Sterile and Fresenius, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity of the '289 patent.

14. Par Sterile is entitled to a declaratory judgment that the '289 patent is invalid.

PRAYER FOR RELIEF

A. A judgment declaring that Par Sterile's importation, manufacture, use, offer for sale, or sale of the product that is the subject of ANDA No. 205366 would not infringe any valid claim of the '289 patent.

B. A judgment declaring all claims of the '289 patent invalid.

C. A decision this case be deemed exceptional under 35 U.S.C. § 285.

- D. Attorneys' fees and costs of suit.
- E. Such other relief as the Court may decide is just and proper.

Dated: July 6, 2015

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(*pro hac vice* applications to be filed)

*Attorneys for Defendants Par Sterile Products,
LLC; Par Pharmaceutical, Inc.; and Par
Pharmaceutical Companies, Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on July 6, 2015, I caused the foregoing to be served on the following people by the following means.

VIA ECF

Donald A. Robinson
Keith J. Miller
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/s/ Peter L. Giunta